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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,649	07/31/2001	Mark J. Feldstein	79,856	1077

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Naval Research Laboratory, Code 1008.2
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Washington, DC 20375-5320

EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,649

Applicant(s)

FELDSTEIN, MARK J.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

3. Determining the scope and contents of the prior art.
4. Ascertaining the differences between the prior art and the claims at issue.
5. Resolving the level of ordinary skill in the pertinent art.
6. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-10, 21-22, 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brody ('404).

8. Brody teaches a device and method for moving fluids in a microfluidic device having fluid channels of less than 1mm across (col. 4, lines 5-6). Fluid can be switched from one flow path to another, mixed and separated (col. 2, lines 37-43). Flow is generated by adjusting the pressure at each of three reservoirs coupled to channels. The source of pressure at each reservoir can be a vacuum pump, atmosphere or a pressure regulator with variable output (bridge col. 4-5) coupled to a switching means, e.g., element 70 to select the pressure at each reservoir. To flow from a first reservoir to another via a "primary channel" without flowing from the second reservoir, $P_1 > P_2$ and $P_3 = P_J$ where P_J is the pressure at the junction (col. 5, lines 45-65). The

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microfluidic switch can be used in a network of channels (col. 7, lines 10-35 and col. 8, lines 30-35) and with a detector (col. 6, lines 40-55). Note that the second reservoir in the instant claims corresponds to the third reservoir in Brody and the primary channel of the instant claims is coupled to the second reservoir of Brody. In the rejection, the examiner has used the terminology of the instant claims, but referenced the corresponding "P" of Brody.

9. Brody fails to explicitly teach an embodiment in which the primary channel is connected to a vacuum source and the first and second reservoirs coupled to atmosphere.

10. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a switchable pressure source including a vacuum source coupled to the primary channel (P2) and a switchable pressure source coupled to atmosphere to first (P1) and second (P3) reservoirs in order to provide $P1 > P2$ to cause flow from the first reservoir to the "primary channel" as taught by Brody. It would have been obvious to switch the pressure source coupled to the second reservoir (P3) away from vent, thereby sealing it, in accordance with equation 2. With respect to claims 3-7, 9-10, it would have been obvious to provide additional chambers and channels in order to provide pre-processing, such as reagent combination, and post-processing, such as separation and/or further reaction, as was known in the art. With respect to claims 13 and 14, flow through channels is inherently related flow resistance and pressure. With respect to claim 29, microfluidic channels have minimal cross-sectional areas.

11.

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12. Claims 11-12, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brody as applied to claims 1-10, 21-22, 26-29 above, and further in view of Heller or Feldstein (Fluorescence Array Biosensor Part 1: Optics and Fluidics).

13. Brody fails to teach a waveguide specific binding sensor.

14. Heller teaches a waveguide specific binding sensor in a microfluidic device.

15. Feldstein teaches a waveguide specific binding sensor in a microfluidic device.

16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a waveguide specific binding sensor in the device of Brody in order to detect biological analytes in a microfluidic device as taught by Heller or Feldstein.

17. Applicant's arguments filed October 21, 2002 have been fully considered but they are not persuasive.

Applicant argues that Brody does not teach or suggest a system in which all the fluid flow can be controlled by a vacuum source without a pressure regulator at each and every reservoir, but the instant claims are not so limited in that the claims do not preclude additional pressure and/or vacuum sources or regulators. Applicant argues that Brody does not teach using a vacuum source and adjustable vents, but Brody teaches connection to vacuum and atmosphere (vent) and means to switch away from atmosphere, constituting an adjustable vent. Applicant argues that Brody emphasizes pressure driven embodiments, but this emphasis does not negate the teaching of vacuum as an alternative to pressurization (column 4, lines 63-67). Applicant argues that Brody does not teach sealed reservoirs with vents that can be sealed and

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unsealed, but the claims are not so limited. Claim 1 only recites an unsealed condition in the functional limitation, and when the reservoirs are open to atmosphere, they are unsealed. Claims 17, 22 and 26 refer to closed and not closed conditions of the vent and the examiner maintains that when the vent is not closed when it is open and closed when the pertinent channel is switched to another pressure source. The claims do not preclude connection to additional pressure sources.

Applicant argues that the examiner has provided no evidence of the motivation to combine Brody with the teaching references, but in the Brody teaches a microfluidic device, which may include an optical detector (e.g., col. 1, lines 10-25), but does not describe a specific optical detector, the examiner looks to the prior art for a teaching of specific optical detectors used in microfluidic devices.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

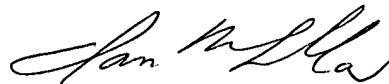
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
January 13, 2003